

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DE SIMONE, C.

Atty. Ref.: 2818-72

Serial No. unknown

Group:

Filed: -December 21, 2001

Examiner:

For: COMBINATION OF LACTIC ACID BACTERIA AND ITS USE FOR THE
PREVENTION AND/OR TREATMENT OF INFECTIONS AND
INFLAMMATORY CONDITIONS

* * * * *

December 21, 2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

In order to place the above-identified application in better condition for
examination, please amend the application as follows:

IN THE SPECIFICATION

Please substitute the following paragraphs in the specification for corresponding
paragraphs previously presented. A copy of the amended specification paragraphs
showing current revisions is attached.

Page 1, before the first line, insert as a separate paragraph:

-- This application is the continuation of international application PCT/IT00/00251
filed 16 June 2000, which designated the U.S.. --

IN THE ABSTRACT

Kindly include the Abstract below:

Abstract

The disclosure is of a combination of lactic acid bacteria comprising: (a) a first component consisting of at least one strain of H₂ O₂-producing lactic acid bacteria; and (b) a second component consisting of at least one strain of arginine-utilizing lactic acid bacteria. The disclosure is also of the use of this combination for making a food supplement, a hygiene product or a pharmaceutical preparation for the prevention and/or treatment of infections and inflammatory conditions caused by bacteria, viruses or fungi, especially in the mouth, vagina, urethra, nose, eyes and ears.

IN THE CLAIMS

Please substitute the following amended claims for corresponding claims previously presented. A copy of the amended claims showing current revisions is attached.

3. Combination according to Claims 1, in which the ratio of the number of bacteria in component (a) to the number of bacteria in component (b) is from 1 : 00 to 100 : 1.
6. Combination according to claim 1 in unit dosage units comprising from 1×10^2 to 5×10^{11} bacteria of component (a) and from 1×10^2 to 5×10^{11} bacteria of component (b).

8. Combination according to Claim 6, in the form of tablets, sucking tablets, sweets, chewing gum, gelatin capsules, pessaries, suppositories and micro-enemas.
9. Combination according to Claim 1, in the form of pellets, dental creams and gels, denture powders, mouthwashes, dentifrices, sprays, suspensions and ointments.
10. Combination according to claim 1, additionally comprising at least one other strain of lactic acid bacteria, chosen from a group made up of *Lactobacillus acidophilus*, *Lactobacillus buchneri*, *Lactobacillus casei*, *Lactobacillus cateniforme*, *Lactobacillus cellobiosus*, *Lactobacillus crispatus*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii*, *Lactobacillus jensenii*, *Lactobacillus leichmannii*, *Lactobacillus minutus*, *Lactobacillus plantarum*, *Lactobacillus salivarius*, *Lactobacillus brevis*, *Lactobacillus gasseri*, *Lactobacillus fermentum*, *Bifidobacterium adolescentis*, *Bifidobacterium angulatum*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium catenulatum*, *Bifidobacterium dentium*, *Bifidobacterium eriksonii*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium plantarum* and *Streptococcus thermophilus*, provided that when component (a) is *Lactobacillus casei* said other strain is not *Lactobacillus gasseri* or *Lactobacillus fermentum* and when component (a) is *Lactobacillus crispatus*, said other strain is not *Lactobacillus fermentum*.
11. Combination according to claim 1, additionally comprising vitamins, quaternary ammonium bases, mineral salts, antioxidants and anti-plaque agents.

14. Use according to Claim 12 for the treatment of the oral cavity as a deodorant, antiinflammatory, anti-caries and/or anti-plaque agent.
15. The composition according to claim 1, wherein component (a) is *Lactobacillus crispatus* and component (b) is *Lactobacillus brevis*.
16. The composition according to claim 1, wherein component (a) is *Lactobacillus salivarius* and component (b) is *Lactobacillus brevis*.
18. The composition according to claim 15, wherein the ratio of the number of bacteria in component (a) to the number of bacteria in component (b) is 1:1.

DE SIMONE, C.
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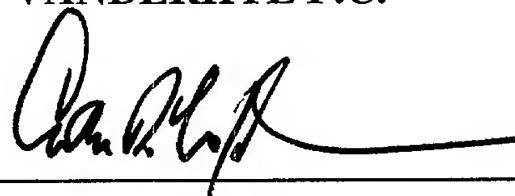
REMARKS

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Page 1, before the first line, insert as a separate paragraph:

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IN THE ABSTRACT

Kindly include the Abstract below:

Abstract

The disclosure is of a combination of lactic acid bacteria comprising: (a) a first component consisting of at least one strain of H₂ O₂-producing lactic acid bacteria; and (b) a second component consisting of at least one strain of arginine-utilizing lactic acid bacteria. The disclosure is also of the use of this combination for making a food supplement, a hygiene product or a pharmaceutical preparation for the prevention and/or treatment of infections and inflammatory conditions caused by bacteria, viruses or fungi, especially in the mouth, vagina, urethra, nose, eyes and ears.

IN THE CLAIMS

3. Combination according to ~~any one of~~ Claims 1-2, in which the ratio of the number of bacteria in component (a) to the number of bacteria in component (b) is from 1 : 00 to 100 : 1.

6. Combination according to ~~any one of the previous claims~~ 1 in unit dosage units comprising from 1×10^2 to 5×10^{11} bacteria of component (a) and from 1×10^2 to 5×10^{11} bacteria of component (b).
8. Combination according to Claim 6 ~~or 7~~, in the form of tablets, sucking tablets, sweets, chewing gum, gelatin capsules, pessaries, suppositories and micro-enemas.
9. Combination according to ~~any one of Claims 1-5~~, in the form of pellets, dental creams and gels, denture powders, mouthwashes, dentifrices, sprays, suspensions and ointments.
10. Combination according to ~~any one of the previous claims~~ 1, additionally comprising at least one other strain of lactic acid bacteria, chosen from a group made up of *Lactobacillus acidophilus*, *Lactobacillus buchneri*, *Lactobacillus casei*, *Lactobacillus catenaforme*, *Lactobacillus cellobiosus*, *Lactobacillus crispatus*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii*, *Lactobacillus jensenii*, *Lactobacillus leichmannii*, *Lactobacillus minutus*, *Lactobacillus plantarum*, *Lactobacillus salivarius*, *Lactobacillus brevis*, *Lactobacillus gasseri*, *Lactobacillus fermentum*, *Bifidobacterium adolescentis*, *Bifidobacterium angulatum*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium catenulatum*, *Bifidobacterium dentium*, *Bifidobacterium eriksonii*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium plantarum* and *Streptococcus thermophilus*, provided that when component (a) is *Lactobacillus casei*

said other strain is not *Lactobacillus gasseri* or *Lactobacillus fermentum* and when component (a) is *Lactobacillus crispatus*, said other strain is not *Lactobacillus fertmentum*.

11. Combination according to ~~any one of the previous claims~~ 1, additionally comprising vitamins, quaternary ammonium bases, mineral salts, antioxidants and anti-plaque agents.

14. Use according to Claim 12 ~~or 13~~ for the treatment of the oral cavity as a deodorant, antiinflammatory, anti-caries and/or anti-plaque agent.

15. The composition according to claim 1 ~~or 2~~, wherein component (a) is *Lactobacillus crispatus* and component (b) is *Lactobacillus brevis*.

16. The composition according to claim 1 ~~or 2~~, wherein component (a) is *Lactobacillus salivarius* and component (b) is *Lactobacillus brevis*.

18. The composition according to claims 15–17, wherein the ratio of the number of bacteria in component (a) to the number of bacteria in component (b) is 1:1.

Abstract

The disclosure is of a combination of lactic acid bacteria comprising: (a) a first component consisting of at least one strain of H_2O_2 -producing lactic acid bacteria; and (b) a second component consisting of at least one strain of arginine-utilizing lactic acid bacteria. The disclosure is also of the use of this combination for making a food supplement, a hygiene product or a pharmaceutical preparation for the prevention and/or treatment of infections and inflammatory conditions caused by bacteria, viruses or fungi, especially in the mouth, vagina, urethra, nose, eyes and ears.

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